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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,577	07/22/2003	Raymond Pratt	109536.183	6543
24395	7590	07/31/2008		
WILMERHALE/DC 1875 PENNSYLVANIA AVE., NW WASHINGTON, DC 20004			EXAMINER ANDERSON, JAMES D	
			ART UNIT	PAPER NUMBER
			1614	
			NOTIFICATION DATE	DELIVERY MODE
			07/31/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/623,577

**Applicant(s)**

PRATT, RAYMOND

**Examiner**

JAMES D. ANDERSON

**Art Unit**

1614

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 06 June 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): The 35 U.S.C. rejection of claims 57-59 is rendered moot in view of Applicant's cancellation of claims 57-59.

6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 36, 37, 39, 43, 45-52 and 54-56.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_

13. ☐ Other: \_\_\_\_\_.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/  
Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because: Ukai et al. teach, suggest, and motivate orally administrable liquid dosage formulations comprising donepezil and the claimed excipients. As such, there is nothing unobvious about the claimed compositions, and Applicants have presented no factual support for their assertion that the bitter taste due to donepezil hydrochloride would not be expected to be present at "neutral and alkaline pH". As noted in the previous Office Action, Ukai et al. teach that the compositions of their invention can be in the pH range of 3-7, which obviates the claimed pH range of 6.5 to 9 and 7 to 8.5 as recited in the instant claims. Applicants further argue that the optimization of the Ukai amounts would lead to increased amounts of polyvinylpyrrolidone rather than the lower amounts as required by the claims. However, Ukai et al. explicitly teach a composition comprising 2% polyvinylpyrrolidone having an average MW of 40,000, which obviates the claimed amounts of polyvinylpyrrolidone. Thus, regardless of the effects of masking an unpleasant taste, Ukai et al. teach, suggest, and motivate one skilled in the art to formulate compositions having the claimed excipients. One of ordinary skill in the art at the time of the invention has the necessary skills and knowledge to adjust the amounts of various excipients in order to formulate the optimal pharmaceutical composition, whether for taste masking or for stability. Applicants have presented no factual evidence that the claimed compositions possess unexpected properties compared to the compositions suggested and motivated by the prior art teachings of Ukai et al.